

ITS MANAGEMENT

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4 August 1993

WEINER ASSOCIATES

Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm 1-23
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Subject: Intent to Amend Laser Performance Standard, Docket 93N-0044

Dear Sir/Madam:

The suggested amendments that were discussed in the 10 May 1993 Federal Register will be a welcome revision to the CDRH requirements. They should compliment the recent changes to the IEC 825 document and thus move toward achieving the goal of one common set of laser safety requirements that apply world-wide. The commitment of the CDRH to harmonization of standards and the dedication of those involved in this effort are greatly appreciated.

There are a few items which require clarification, and the following comments are provided to match the item numbers in the Notice of Intent:

2. Suggest to clarify the last sentence of the first paragraph as follows: "However, for products for which long-term viewing or exposure is". . . . [to differentiate between products in which viewing or exposure would only occur for short periods] .

It is assumed that products which emit in the **near-IR** range and which are, in effect, classified on the basis of 100 s would continue to be so classified, even if they are general purpose products.

Surveying lasers should not be included in the **category** with laboratory laser **systems** for a 10,000 s classification period, as they are not intended to be viewed for long durations. Also, it would help to clarify the proposal to add "general construction" to the applications listed for use with the 100 s classification time.

4. This change should be included only if the change to reduce the time period for classification in item 2 is also made. If this change was made without reducing the time period for classification, the result would be a lowering of the allowable power for some products and an inconsistency with the IEC 825 standard.

Suggest to revise the first sentence: "...AEL of Class I for products with scanning or repetitively pulsed outputs." [to clarify that this would apply also to scanning products] .

93N-0044

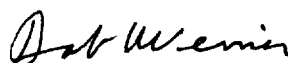
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8. It would be helpful to clarify that condition 1) refers only to Class IIIa radiation that is emitted out, not just any radiation level [if that is the intent of the proposal] . It should be noted that this condition apparently goes beyond the interlock requirements in Amendment 2 to IEC-825.
10. This would appear to require the indicator to be on only when an aperture is actually emitting energy. That goes beyond the requirement in IEC Amendment 2 which requires only that the indicator show when an aperture Could be emitting energy. There was concern expressed during the drafting of the IEC amendments [Ref: IEC document 76(Kobe/UK)21] that an indicator that is lit only when there is energy being emitted out of an aperture would be difficult to implement and may not provide additional safety for the user.
12. The acceptance of IEC labels will ease the burden on manufacturers. I share the concern, however, that the differences in measurement criteria for classification between the IEC and CDRH standards may cause problems and confusion. Perhaps this can be addressed in the third set of amendments to the IEC standard.
13. This is a welcome suggestion, however, in order to provide consistency it should also apply to the labels in 1040.10 g(7) .
14. This is an excellent suggestion. Hopefully the effort that is underway for the third set of amendments to IEC 825 will result in simplified wording and/or symbols that can be incorporated into the CDRH laser performance standard.

In closing, as a consultant to hundreds of laser product manufacturers, I wish to emphasize the desirability of these changes and to express a wish for an accelerated review and approval process to minimize the time that manufacturers must continue to deal with conflicting sets of requirements. It is also hoped that the changes in CDRH procedures will be approved that were discussed in items 1 & 17 of the September 23, 1992 Notice of Consideration.

If you would like any clarification on these comments, please contact me.

Yours truly,

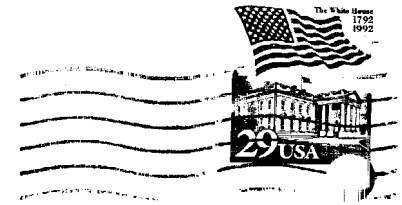


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